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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/616,321 | 07/07/2003 | Dallas L. Clouatre | | 1306 |

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Patent Administrator
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| EXAMINER | |
|---|---|
| SOROUSH, LAYLA | |
| ART UNIT | PAPER NUMBER |
| 1617 | |

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/616,321 | CLOUATRE, DALLAS L. | |
| | Examiner | Art Unit | |
| | Layla Soroush | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Priority***

The Office Action is in response to the Preliminary Amendment filed July 7, 2003. Claims 1-6 are pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because while the specification is enabled for unhealthful weight loss the specification does not reasonably provide enablement for treatment or ameliorating cachexia and health-threatening catabolism in an individual. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification is enabled for the treatment of weight loss, it does not provide sufficient information that cachexia and health-threatening catabolism are treatable using the method of administering orally an effect amount of

(--)-hydroxycitric acid. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Analysis of In re Wands are listed below:

(1). The Nature of the Invention: Claims 1-6 are drawn to an invention which pertains to "a method for treating or ameliorating cachexia and health-threatening catabolism in an individual in need thereof which is comprised of administering orally an effective amount of (-)-hydroxycitric acid."

(2). The state of the prior art: The state of the art regarding treatment or amelioration of cachexia and health-threatening catabolism is relatively high.

(3). The predictability or unpredictability of the art: The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for treatment or amelioration of cachexia and health-threatening catabolism. The general treatmnet of weight loss is different from the treatment or amelioration of cachexia and health-threatening catabolism. Cachexia and health-threatening catabolism require different therapies, and take into consideration various factors. the specification is viewed as lacking an adequate enablement of where cachexia and health-threatening catabolism may be actually treated.

(4). The breadth of the claims: The claims encompass a method for the treatment or amelioration of cachexia and health-threatening catabolism comprising orally administering an effective amount of (-)-hydroxycitric acid. Applicant fails to set forth the criteria that define the treatment of the diseases.

(5). The amount of direction or guidance presented: While the specification is enabled for the treatment of weight loss, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of treating or ameliorating cachexia and health-threatening catabolism. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed composition including (-)-hydroxycitric acid as an active ingredient for cachexia and health-threatening catabolism.

(6). The presence or absence of working examples: Applicant does not provide any working examples for the treatment of cachexia and health-threatening catabolism. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the treatment effects of the instant composition.

(7). The quantity of experimentation necessary: The quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples," "the level of skill in the art" and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

In view of the breadth of the claims, unpredictability of treatment or amelioration of cachexia and health-threatening catabolism, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention of claims 1-6.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Triscari et al (Lipids; 4/1977—IDS).

Triscari et al. teaches hdroxycitrate has been demonstrated to show both inhibition of lipid synthesis and the stimulation of fatty acid synthesis. Following the experimental testing, using oral administration of HCA to fed rats, it was found that stimulation in some site in the lipogenic pathway occurs because there is an increase of [3H]2O label, indicative of increase in fatty acid and cholesterol synthesis. Further, (-)-Hydroxycitric acid (HCA) is shown to activate acetyl CoA carboxylase, stimulating rather than inhibiting lipid synthesis. The reference generally teaches HCA used in the method of stimulating lipid synthesis, therefore, the species of free acid are rendered obvious by the prior art teachings.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Triscari et al. and treat weight loss using (-)-Hydroxycitric acid. The motivation to make such an incorporation is because of the teachings by the reference that HCA stimulates lipid synthesis. Therefore, a skilled artisan would have reasonable expectation of treating weight loss with the compound as claimed.

Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Triscari et al (Lipids; 4/1977—IDS) as applied to claims 1 and 2 above, in view of Balasubramanyam et al. (US Pat No. US 6160172 A) and further in view of Ansel et al. (.Pharamceutical Dosage Forms and Drug Delivery Systems; 7th Edition; 1999).

Triscari et al. is as discussed above.

Triscari et al. does not teach the salts of alkali metal salts of HCA nor a controlled release form as recited in claim 6.

Balasubramanyam et al. teaches the sodium salt of hydroxcytric acid.

Ansel et al. teaches various salt doses of pharmaceuticals are common in the art. Specifically, Ansel et al. teaches "sodium and potassium salts of weak organic acids and hydrochloride salts of weak organic bases dissolve much more readily than do the respective free acids or bases." Additionally, the reference teaches "a drug may interact with one of the other agents present to form a chemical complex which may result in reduced drug solubility and decreased drug absorption."

It would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Balasubramanyam et al. and Ansel et al. into the composition. The motivation to incorporate the sodium and potassium salts is because Balasubramanyam et al. teaches the sodium salt of hydroxycitric acid and Ansel et al. teaches the salts dissolve much more readily than do the free acids or bases. Therefore, the skilled artisan would have reasonable expectation of successfully producing a composition that dissolves more readily.

Additionally, Ansel et al. teaches various extended release tablets and capsules are known in the art (p.230). Such extended release formulations include controlled release (or modified release) forms.

It would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Ansel et al. into the composition. The motivation to incorporate controlled release (or modified release) forms is because of Ansel et al.'s teachings that the said forms have "drug release features based on time, course, and/or location which are designed to accomplish therapeutic or convenience objectives not offered by conventional or immediate-release forms." A skilled artisan would have reasonable expectation of successfully producing a therapeutic composition that "promptly produces the desired therapeutic effect which then is followed by the gradual and continual release of additional amounts of drug to maintain this effect over a predetermined period of time," reduces drug blood level fluctuations, reduces the frequency of dosings, and reduces adverse side effects of drugs (p.230 and 231).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Triscari et al (Lipids; 4/1977—IDS) as applied to claims 1 and 2 above, in view of Sharma et al. (EP 0866137 A1) and further in view of Makino et al. (US Pat. No. 5433959)

Triscari et al. does not teach the alkaline earth metal salts of HCA, such as calcium or magnesium salts.

Sharma et al teaches the calcium salt of hydroxycitric acid.

Makino et al. teaches a pharmaceutical composition which comprises basic inorganic salts. Makino et al. teaches magnesium and calcium basic inorganic salt are particularly useful stabilizing agents.

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Sharma et al. and Makino et al. into the composition. The motivation to incorporate the magnesium and calcium is because Sharma et al. teaches the calcium salt of hydroxycitric acid and Makino et al. teaches the salts are particularly useful stabilizing agents. The skilled artisan would have reasonable expectation of successfully producing a stabilized composition.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Triscari et al (Lipids; 4/1977—IDS) as applied to claims 1 and 2 above, and further in view of Janiak (US Pat. No. 3592890).

Triscari et al. does not specifically teach the salts of alkali metal salts or alkaline metal salts of HCA or a mixture thereof.

However, Janiak teaches suitable salts of a pharmaceutical composition are sodium, potassium, calcium, magnesium, or aluminum. A mixture of potassium salt and sodium salt is an especially suitable form of the composition.

It would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Janiak into the composition. The motivation to incorporate mixture of salts is because Janiak teaches the potassium salt and sodium salt is an especially suitable form of the composition. The skilled artisan would have

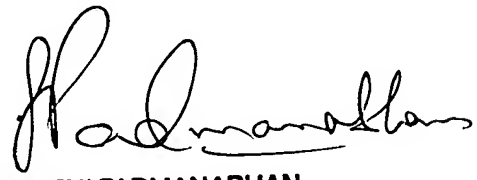
reasonable expectation of successfully producing a more stable aqueous solution at concentrations up to 20% as taught by the prior art reference.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER